The Mediating Effect of Distress Caused by Constipation on Predictors of Quality of Life of Hospice Patients with Cancer.

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The Mediating Effect of Distress Caused by Constipation on Predictors of Quality of Life of Hospice Patients with Cancer

by

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy
College of Nursing
University of South Florida

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Dedication

To my wife and parents whose support and encouragement have always been the light at the end of the tunnel. And to my lovely daughter, Zaina.
Acknowledgments

I would like to express my deepest gratitude to my advisor Dr. Susan McMillan, I consider her both a mentor and a family. Her work ethic was a guide for me throughout this work. She taught me the fundamentals of research and provided much needed help whenever I needed.

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My precious family with their love, patience and all kinds of support is something I would never forget. Finally, I would like to remind our terminally ill cancer patients that life is not a problem to be solved; life is a gift to be enjoyed.
# Table of Contents

List of Tables.................................................................................................................. iii

List of Figures................................................................................................................ iv

Abstract........................................................................................................................... v

Chapter One: Introduction............................................................................................... 1
  Statement of the Problem................................................................................................. 4
  Research Questions.......................................................................................................... 5
  Conceptual Framework.................................................................................................... 5
  Definition of Variables.................................................................................................... 6
  Significance of the Study................................................................................................. 8

Chapter Two: Review of Literature.................................................................................... 10
  Predictors of Quality of Life in Cancer Patients
    Near the End of Life....................................................................................................... 10
    Symptom Severity, Distress and Quality of Life........................................................ 13
    Constipation and Cancer.............................................................................................. 15
    Constipation and QOL Among Cancer Patients.......................................................... 16
    Summary...................................................................................................................... 17

Chapter Three: Methods................................................................................................. 18
  Research Design............................................................................................................ 18
  Sample and Setting........................................................................................................ 18
  Instruments.................................................................................................................... 19
    The Memorial Symptom Assessment Scale (MSAS).................................................. 19
    The Hospice QOL Index-14 (HQLI-14).................................................................... 19
    Palliative Performance Scale (PPS)............................................................................ 20
    Short Portable Mental Status Questionnaire (SPMSQ)............................................. 20
    Demographic Data Form............................................................................................. 21
  Procedures..................................................................................................................... 21
  Data Analysis................................................................................................................ 21
<table>
<thead>
<tr>
<th>Chapter Four: Results</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>23</td>
</tr>
<tr>
<td>Descriptive Statistics</td>
<td>23</td>
</tr>
<tr>
<td>Correlations</td>
<td>25</td>
</tr>
<tr>
<td>Predictors</td>
<td>26</td>
</tr>
<tr>
<td>Mediation</td>
<td>26</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter Five: Discussion, Conclusions and Recommendations</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion</td>
<td>30</td>
</tr>
<tr>
<td>Conclusions and Recommendations</td>
<td>34</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>References</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>36</td>
</tr>
</tbody>
</table>
List of Tables

Table 1: Frequency and Percent of Patients by Demographic Variables.................... 24

Table 2: Means and Standard Deviations of Patients’ Age, Education, PPS Scores, Constipation Severity Scores and Constipation Distress Scores................................................................. 25

Table 3: Pearson Correlation Coefficients between the Predictors and the QOL....... 27

Table 4: Direct, Partial, and Total Effects of Bootstrapping Mediation Analysis............................................................... 28
List of Figures

Figure 1: Conceptual framework.................................................................................. 7
Abstract

Key positive outcomes for hospice patients include the prevention and alleviation of physical and psychological distress, maintenance of physical and mental functioning and all aspects of quality of life. This research used secondary analysis of previously gathered data to answer new research questions with alternative strategies to examine relationships not previously analyzed. The researchers collected data from 717 cancer patients who had been admitted to one of two private hospices. The aim of their experimental intervention was to define the effectiveness of using standardized assessment tools to provide systematic feedback to hospice staff about hospice patients and their caregivers. The aim of this secondary analysis was to assess the mediating effect of constipation distress on the relationship between constipation intensity and the hospice patients’ QOL. Variables included in the analysis were: Quality of Life, Constipation Distress, Sociodemographic Characteristics (Age, gender, marital status, race/culture, education, and socioeconomic status), Clinical Characteristics (Type of cancer, Co-morbidities, Functional/mental Health status), and Constipation Intensity.

The data analyzed using descriptive statistics, including the frequency, percentage, means and standard deviation for quality of life. A relationship between quality of life and sociodemographic variables and between quality of life and clinical characteristics were evaluated with Pearson correlation coefficients. An exploratory mediation analysis was used to assess the mediation effect of the constipation distress.
Results showed that age, ethnicity, constipation severity and functional status were predictors of QOL (P<0.0), and the bootstrapping showed that constipation distress has a mediation effect on the relationship between constipation severity and quality of life. The symptom intensity and distress as well as the relationship between constipation and quality of life need to be seen in a holistic approach to achieve the best symptom management for cancer patients.
Chapter One: Introduction

Globally, cancer is recognized as a major public health concern. According to the American Cancer Society, more than 1.5 million new cancer cases and 570,000 cancer-related deaths occur annually in the United States (Jemal, et al., 2008). Constipation is a common problem for cancer patients, and is a frequent adverse effect of cancer-associated pain treatment with opioid analgesics (Mercadante, Ferrera, & Casuccio, 2011). Constipation increases the burden on cancer patients by affecting their overall quality of life (QOL) and increasing their level of pain and distress. As a result of severe constipation, patients complain of gastrointestinal tract problems such as vomiting and hemorrhoids which lead to increased emergency room visits and hospitalizations. Constipation burden does not affect the patient alone; it also increases the burden on the families as well as health care system costs (Librach, et al., 2010).

More than 60% of patients with constipation are inadequately treated because of the under-estimation of constipation intensity and ineffective treatment. In some cases, no treatment is given at all (Laugsand, Jakobsen, Kaasa, & Klepstad, 2010). It is estimated that more than 40% of cancer patients with opioid-related constipation may not be receiving laxatives as prophylaxis, and their constipation may not be managed properly. These patients report discomfort, distress and pain (Wee, et al., 2010). Patients with severe constipation have a lower QOL and higher treatment costs (Hjalte, Berggren, Bergendahl, & Hjortsberg, 2010).
Constipation is a serious problem for cancer patients near the end of life, but the literature does not address the distress caused by constipation and the effect of this distress on the QOL of patients with advanced cancer. Symptom distress is a component of the broader, multidimensional construct of the symptom experience (Goodell & Nail, 2005). Symptom distress is the degree of discomfort associated with a symptom as experienced by the patient, and it reflects the patient's interpretation of a symptom (Molassiotis, Wengstrom, & Kearney, 2010). Symptom distress is defined as "the degree of perceived discomfort experienced in relation to a symptom" (Cimprich, 1999).

The patient’s experience of symptoms consists of physiological and psychological dimensions, this is why patients develop a response to their symptoms based on what meaning they attribute to them. One of the main dimensions of the symptom experience is distress. Higher levels of symptoms severity have been predictive of higher levels of symptom distress and poor quality of life (Bevans, Mitchell, & Marden, 2008).

Patients' symptom experiences are known to be their perception and response to symptom occurrence and symptom distress. Symptom occurrence measures the prevalence of the symptom. Symptom distress is the amount of physical and/or mental upset that patient’s experience (Rhodes, McDaniel, Matthews 1998). QOL is a multifaceted concept with a variety of domains. Depending on the investigators, these domains might include psycho-physiological, functional, and social/spiritual well-being (Aaronson et al., 1993, Cohen et al., 1997, Ferrans, 1990; McMillan et al., 2006).

Palliative care and hospices have developed rapidly since the late 1960s. The pioneering work of Dr. Cicely Saunders was instrumental in drawing attention to the end-
of-life care needs of patients with advanced malignant disease. Palliative care began to be defined in the 1970s and came to be synonymous with the physical, social, psychological, and spiritual support of patients and significant others with life-limiting illness, delivered by a multidisciplinary team. Palliative care services have developed in many settings and have often been closely related to oncology. The global need for this type of care remains much greater than what is currently available. However, there are encouraging signs of recognition by policymakers and influential bodies, and interest in palliative care has never been greater (Clark, 2007).

Hospices provide palliative care with the goal of improving patient QOL. A critical component in improving QOL is aggressive management of physical symptoms. Physical symptoms most commonly experienced by cancer patients are reported to include fatigue, dyspnea, pain and constipation (Donnelly & Walsh, 1995; Weitzner, Moody & McMillan, 1997). Constipation causes some degree of symptom distress and has a negative effect on the patient’s overall QOL. In a study of 393 patients with cancer, patients ranked constipation control as sixth in importance out of 25 items related to overall QOL (Stark, Tofthagen, Visovsky, & McMillan, 2012). Uncontrolled symptoms clearly have a negative impact on all aspects of QOL, including emotional and spiritual well-being, social relationships, and functional ability (Kurtz, Kurtz, Given, & Given, 1993; McMillan & Weitzner, 1998). Most clinicians and researchers agree that improvement in the patient's QOL is the ultimate goal in care of cancer patients near the end of life, and this is consistent with the approach of the World Health Organization (WHO). The expected outcome of palliative and hospice care is to control patients’
symptoms to ensure a high level of QOL in all its dimensions (Berger, Shuster, & Von Roenn, 2006).

Palliative care is a young discipline for research, though expert opinions have been helpful. The lack of extended research programs addressing basic biological mechanisms of patients with advanced disease and short life expectancy nationally has created an increasingly strong call for research in palliative care. Obstacles and challenges include ethical concerns about collecting data from these very ill patients, establishment of a research agenda, the number of experienced researchers available at the university level, and funding for palliative care research. Committed individuals have conducted important research, and if their efforts are combined with professional leadership, funding might be secured to establish the programs necessary to address palliative care research (Kaasa & Dale, 2005).

**Statement of the Problem**

Constipation is among the more common symptoms that require recognition and treatment, and one that is known to be negatively correlated with quality of life (McMillan & Weitzner, 1998). The literature addressing whether there is an effect of constipation distress as a predictor of hospice patient’s quality of life is very limited, despite it being a significant problem for cancer patients near the end of life. Crucial positive outcomes for hospice patients include prevention and alleviation of physical and psychological distress, maintenance of physical and mental functioning and support for all aspects of QOL. Nurses encounter patients with constipation in a variety of practice settings; and have a pivotal role in identifying patients at risk and implementing
evidence-based interventions (Woolery et al 2008). Nurses are instrumental in control of constipation, and enhancing QOL in patients with advanced cancer (Fredericks, Hollis, & Stricker, 2010). The purpose of the proposed study was to determine, using an existing data set, predictors of QOL and to evaluate the mediating effect of constipation distress in patients who receive homecare from a large nonprofit hospice.

**Research Questions**

This study addressed the following questions:

1. Do socio-demographic variables (age, gender, marital status, race/culture, education, and socioeconomic status), clinical characteristics (type of cancer, physical and mental status) and constipation intensity predict quality of life in hospice patients with cancer?

2. To what extent does constipation distress serve as a mediator in the relationship between constipation intensity and overall quality of life in hospice patients with cancer?

**Conceptual Framework**

Constipation causes symptom distress and has a negative effect on the patient’s overall QOL. This framework posits that there is a direct path and effect between constipation intensity and the patient’s overall QOL with and without the distress being a mediator in the relationship. In the past, the social sciences considered the terms mediator and moderator to be synonymous (Baron & Kenny, 1986). Contemporary thought considers mediation as a variable that accounts for all or part of the relationship.
between a predictor variable and outcome. A mediator also can be explained as a
transmitter of the effect of an independent variable (IV) on a dependent variable (DV). So
the IV affects the DV because the IV affects the mediator, and the mediator in sequence
affects the DV. (Preacher, Rucker, & Hayes, 2007). Statistical significance of the
mediated effect can be calculated by dividing the estimate by its standard error and
comparing the result with the standard normal distribution. For non-normality of data,
both confidence limits for mediated effects and resampling methods could be used
(MacKinnon & Fairchild, 2009).

The aim of end of life care is to enhance QOL for patients; QOL is valued as a
primary outcome. Several domains contribute to an individual’s overall QOL. These
include psychophysiological, functional, and social/spiritual well-being (McMillan &
Weitzner, 1998). A conceptual framework for evaluating QOL of cancer patients is very
important because it structures assessment of all domains and predictors and can quantify
an individual patient's QOL through sociodemographic and clinical characteristics. In
addition, it may determine relationships between symptom distress caused by
constipation and cancer patient's quality of life.

**Definition of Variables**

For the purpose of this study the following terms are defined:

1. **Quality of Life (QOL)** is a multifaceted concept with a variety of domains.
For the purpose of this research, these domains include psychophysiological, functional,

Figure 1 Conceptual framework

2. Patients’ symptom experiences are known to be their perception and response to symptom occurrence and symptom distress.

3. Symptom occurrence is the frequency and severity of the symptom.
4. Symptom distress is the amount of physical and/or mental upset that may experience by patients (Rhodes, McDaniel, Matthews 1998). Symptom distress is a component of the broader, multidimensional construct of the symptom experience (Goodell & Nail, 2005). Symptom distress is known as the degree of discomfort associated with a symptom as experienced by the patient, and it reflects the patient's interpretation of a symptom (Molassiotis, et al., 2010). Symptom distress also is defined as "the degree of perceived discomfort experienced in relation to a symptom" (Cimprich, 1999).

**Significance of the Study**

There is a paucity of extant literature addressing the effect of constipation as a predictor on hospice patient’s quality of life. However, constipation is a significant problem for cancer patients near the end of life (Garrison, Overcash, & McMillan, 2011). Expert opinion has been always useful for the palliative care discipline because so few studies have been conducted in this population; this highlighted the importance of having more research on the national level (Kaasa & Dale, 2005).

Results of this secondary analysis may provide nurses with more knowledge about the impact of symptom distress in cancer patients, and its relationship with cancer patient's quality of life. Availability of skillful supportive care is a right for cancer patients near the end of life and their families. Results of this study may influence curricular changes. In the field of education, both educators and professionals should start to change the curriculum for all university levels; graduate and undergraduate, and for continuing education departments at hospitals and hospices to insure that health care
provider's skills and knowledge are based on evidence. Nurses and other health care providers should be committed to improving care for their patients and alleviating suffering for cancer patients near the end of life by managing their symptoms.
Chapter Two: Review of Literature

The literature review is divided into four sections: First, predictors of QOL are addressed; second, symptom distress and QOL in cancer patients near the end of life are discussed. The third section of the literature review addresses constipation and cancer, and finally the relationship between constipation and QOL are presented.

Predictors of Quality of Life in Cancer Patients Near the End of Life

Previous research indicates that a number of variables may affect QOL in persons with cancer. Age has often been found to be a significant predictor with older patients reporting higher QOL scores (Hack et al., 2010; Wald et al., 2007; Salonen, Kellokumpu Lehtinen, Tarkka, Koivisto, & Kaunonen, 2011). A longitudinal study was conducted to evaluate sarcoma patients’ QOL and to explore their demographic and clinical predictors of QOL (Paredes, Pereira, Moreira, Simões, & Canavarro, 2011). Researchers used a structured questionnaire to collect demographic and clinical data. The sample ages ranged from 18-72 years. The majority of patients were exposed to chemotherapy during their treatment phase, and 25% were exposed to radiation therapy. Patients scored low QOL at baseline and treatment phase, QOL scores in the physical domain at baseline were a significant predictor ($p = 0.01$) for physical functioning at treatment phase while age ($p = 0.26$) marital status ($p = 0.09$), and professional status ($p = 0.55$) contributed to a significant increase in the total of explained variance. Also there was a significant
relationship between symptoms such as pain and fatigue with low financial status at both baseline and after treatment.

Predictors of QOL including patient age, education, place of living, tumor grade and impact of initial treatment were studied by Hack and colleagues (2010). They also explored the interaction between predictors of distress and quality of life for cancer patients receiving treatment. They reported a significant main effect of chemotherapy on patients’ QOL, and age was a significant predictor of emotional wellbeing ($p<0.0001$). Younger women reported worse QOL than older women. The researchers concluded that a combination of patient factors such as older age and lack of education or lack of support leads patients to withdraw as an adaptation mechanism to stressful situations (Hack et al., 2010).

Gender also has been studied in relation to QOL. Females reported worse QOL, and a combination of being older women and lack of support and lower education level led to lower QOL scores (Hack et al., 2010; Zimmermann et al., 2010). Mystakidou and colleagues (2005) evaluated the relationship between psychological morbidity, anxiety and depression in 120 patients receiving palliative care. Strong relationships between hospital anxiety and depression and patients’ emotional functioning ($p<.0005$) were found. The influence of gender on physical, emotional, and social functioning and other symptoms was high ($p<.05$) (Mystakidou et al., 2005).

Contemporary research indicates that patients who are employed report a lower risk for undesirable changes in QOL than patients who are retired or unemployed; and employed women have a better QOL than unemployed or retired women (Salonen,
Kellokumpu Lehtinen, Tarkka, Koivisto, & Kaunonen, 2011; Kandasamy et al 2011). A randomized, control trial conducted by Salonen et al. (2011) reported significant predictors of patients’ QOL to be: level of education, employment status, having children, and exposure to cancer treatments. QOL of both the intervention and control groups of patients improved over the six-month after surgery. Body image was significantly reduced for both the intervention (p = 0.001) and control groups (p = 0.007). Significant systematic adverse effects were noted in the intervention group (p \leq 0.001) and in the control group (p = 0.003).

Although some have stated that the SF-36 is not a measure of QOL because it measures only physical and mental well-being, investigators continue to use it. Using the SF-36, employed subjects scored higher on QOL than unemployed or retired subjects. Scores for employed subjects ranged around 50 in all scales while they were between 30 and 40 for the unemployed. QOL scores were lower for subjects who were living alone compared to those who are living with families or partners especially for general health and social functioning scales of SF-36. (Wald et al., 2007).

Georges, Onwuteaka-Philipsen, Heide, Wal and Maas. (2005) studied cancer patients and their characteristics in their last days in a study designed to assess symptoms and symptom management. Results showed a significant increase in symptoms such as loss of appetite, feeling unwell, dependency and fatigue. Physicians reported that patients’ physical symptoms were managed more than their psychosocial symptoms. The number of medical specialties that provide care for dying patients in their last days decreased, while other non-medical caregivers increased. The study supported that the
participation of family members supported the terminally ill cancer patients and facilitated their dying in peace.

Mental status has been assessed both as cognitive decline and mental well-being (Reid-Arndt, Hsieh, & Perry, 2010; Wald et al, 2007). Reid et al (2010) assessed the effect of delicate cognitive changes on breast cancer patients’ QOL. Demographic information, neuropsychological measures, self-reported cognitive difficulties, fatigue and social support seeking were predictor variables. The results confirmed how important social support was to QOL. Also analysis shown an inverse relationship between self-reported cognitive complaints and overall QOL ($p = 0.08$). Psychological morbidity was largely predicted by QOL dimensions ($p < .05$) (Mystakidou et al., 2005). Also significant correlations have been found between QOL and physical status (Garrison, Overcash, & McMillan, 2011). Although QOL has been studied in different nations, research comparing cancer patients from different cultural groups are limited (Wald et al., 2007).

**Symptom Severity, Distress and Quality of Life**

Researchers indicated that patient symptoms are not being successfully managed, Symptom distress in persons with cancer has been shown to have a negative effect on overall QOL (McMillan, 2002; Gapstur, 2007).

Some studies have shown that women report greater symptom distress than men ($p = 0.005$) (Zimmermann et al. 2010). Karabulu, Erci, Ozer, and Ozdemir (2010) conducted a cross-sectional study to identify the prevalence and severity of cancer patients’ symptoms. In this study 12.5% of patients experienced severe symptoms, while
37.5% experienced moderate symptoms. The most frequently reported symptoms among a sample of hospice patients with cancer were lack of energy, pain, dry mouth, and shortness of breath. The average intensity score was 3.13 (McMillan & Small, 2002).

To evaluate the incidence and severity of constipation in hospice patients, researchers at the University of Texas conducted a large retrospective cohort study in a large population-based sample of 50,641 persons who received hospice care. Moderate to severe constipation was most dominant among terminally ill cancer patients, mostly patients who were diagnosed with respiratory cancers, gastrointestinal or peritoneum cancers, and genitourinary organs cancer. Constipation was also highly reported by patients with high pain scores or patients on laxatives (Strassels, Maxwell, & Iyer, 2010).

Researchers conducted a cross-sectional study to evaluate the effect of spiritual wellbeing on the rest of QOL dimensions, depression, and symptoms of distress in terminally ill cancer patients (Kandasamy, Chaturvedi, & Desai, 2011). The results showed that spiritual well-being correlated negatively with mood ($r = -0.630, p < 0.001$), work ($r = -0.376, p < 0.001$), relationships ($r = -0.624, p < 0.001$), and enjoyment of life ($r = -0.681, p < 0.001$). Spiritual well-being positively correlated with all the other aspects of QOL measures $p = 0.008$. Patients experiencing stress and anxiety experience significantly lower quality of life levels. (Mehnert, Lehmann, Schulte, & Koch, 2007).

Kirkova et al. (2009) conducted another study to determine the relationship between symptom severity and distress from multiple symptoms in cancer, and to evaluate the relationship between participants’ demographics and symptom distress. Results showed that more than 50% of symptoms reported as distressful, younger patients
and females showed higher levels of distress except for anxiety, the primary site group
does not affect distress, and the prevalence of distress increased with greater symptom
severity.

McMillan and Small (2002) evaluated symptom distress and quality of life in
patients with cancer newly admitted to hospice home care. The results showed that lack
of energy caused the greatest distress, followed closely by dry mouth and pain. The
results of the regression analysis indicated constipation intensity was related to QOL at
the univariate level. When all predictors were considered simultaneously, only the total
distress score remained a significant predictor of QOL ($p < 0.001$), accounting for about
35% of variance. The authors concluded that QOL was affected by symptom distress in
people with advanced cancer near the end of life.

To study the incidence and character of problems relating to cancer and treatment
and their association with symptom distress a group of researchers Recommendations
were made for health care professionals to consider family caregiver’s assessments of
patients’ symptom distress when the patient is unable to provide his/her own symptom
distress self-report. A percentage of 53% of patients reported experiencing emotional
distress and/or anxiety related to prostate cancer (Mehnert, Lehmann, Schulte, & Koch,
2007).

**Constipation and Cancer**

Constipation is common in patients with cancer because of their many risk
factors, and in a cancer patient receiving opiates, constipation is inevitable.
Unfortunately, this potentially serious problem is often overlooked and under-managed.
It is known that constipation causes symptom distress, and this distress affects the QOL of cancer patients and their caregivers (Kinzbrunner, Weinreb, Policzer 2002; Ferrell, Coyle 2006).

In a descriptive cross-sectional study conducted in palliative care settings in Spain, researchers aimed to evaluate the effectiveness of laxative treatment and if there is a relationship between constipation and opioids. In this study 91% patients were diagnosed with cancer and the constipation prevalence was the highest among them (Noguera, Centeno, Librada, & Nabal, 2010).

The impact of opioid induced bowel dysfunction in patients treated with opioids for pain and were on laxative has been assessed by a multinational survey online designed by Bell, Panchal, and Miaskowski (2009). The bowel dysfunction symptoms reported in this study by most patients four times a week with a highest severity, and also patients stated the impact of bowel dysfunction on their daily life activities and so on their quality of life. Around 30% of patients neglected their opioids doses or started noncompliance with this treatment in order to have better bowel motility. This study supported the idea that the opioid induced bowel dysfunction incidence is high even the patients taking laxative and patients experienced new symptoms in addition to uncontrolled pain that affects the level of their quality of life.

**Constipation and QOL Among Cancer Patients**

Wald et al. (2007) studied QOL in a multinational survey to compare different social and demographic groups with and without constipation and to detect country-
specific differences among the groups studied, and to assess the impact of constipation on quality of life. Health-related QOL (HRQOL) was assessed with the Short Form 36 (SF-36) questionnaire in 2870 subjects in France, Germany, Italy, UK, South Korea, Brazil and USA. Results in all countries showed that QOL scores correlated negatively with age, and there were significant differences in HRQOL between constipated and non-constipated individuals and a significant, negative correlation between the number of symptoms and complaints and SF-36 scores. The study showed also a significant relationship between constipation and QOL and the influence of social and demographic factors on HRQOL in constipated people.

Chronic constipation will lead to incapacitating symptoms. Health care providers usually failed to treat constipation with laxatives, causing negative effects on the patients quality of life (Quigley, Vandeplasche, Kerstens and Ausma, 2009; Outryve, Beyens, Kerstens, and Vandeplasche, 2009; Tong, Isenring and Yates, 2009).

Summary

The literature showed a significant relationship between constipation and QOL and an influence of social and demographic factors on QOL of constipated patients. The distress caused by constipation has an impact as well on patients’ QOL.

Constipation is a serious problem for cancer patients near the end of life, but the literature does not address the distress caused by constipation and the effect of this distress on hospice patient's quality of life. Thus, there is a need for further clarification of constipation and predictors and outcomes connected with it.
Chapter Three: Methods

Research Design

This chapter presents the methods used in this study. This study was a descriptive, correlational design and a secondary analysis of data from an earlier study (McMillan, Small, & Haley, 2010). The aim of the original experimental intervention study was to evaluate the effectiveness of using standardized assessment tools in order to provide systematic feedback from hospice patients and their caregivers. The researchers hypothesized that there would be significant differences in hospice outcomes between the experimental and the control groups. The researchers used data from 709 cancer patients and their caregivers who had been admitted to one of the two large private not-for-profit hospices. In both settings the patients received comprehensive services delivered by the hospice Interdisciplinary teams. This proposed project is a non-experimental quantitative study using previously gathered data to test a new hypothesis with alternative strategies to examine relationships not previously analyzed.

Sample and Setting

The target population was patients who receive homecare from a large nonprofit hospice; the convenience sample was 310 patients. Power analytic techniques indicated that with the sample size, with power set at .90 and alpha set at .05, a small to medium effect size could be detected. In this study, all patients met the following inclusion
criteria; adults diagnosed with cancer who had an identified family caregiver; patients who were able to read and understand English, and able to pass mental status screening. The setting for the study was two large nonprofit hospices that primarily provide home care. The study was approved by the Hospice Bioethics Committees and the University Institutional Review Board.

**Instruments**

Five instruments were used in this study to operationalize the variables of interest. They were the Memorial Symptom Assessment Scale, the Palliative Performance Scale, the Short Portable Mental Status Questionnaire, the Hospice Quality of Life Index, and a Patient Demographic Date Form.

**The Memorial Symptom Assessment Scale (MSAS).** The MSAS was used to measure constipation symptom presence, intensity and distress. Twenty-five symptoms are measured, including constipation. Patients mark the form indicating which symptoms they are currently experiencing. Item scores for both intensity and distress range from 0 to 4 with 4 being greater intensity or distress due to constipation. The construct validity was evaluated by correlating MSAS scores and quality of lifeQOL. As predicted, there was a strong negative correlation (r=-0.72). Coefficient alpha was used to evaluate reliability and it was good (r= 0.73-0.74) (McMillan & Small, 2002).

**The Hospice QOL Index-14 (HQLI-14).** is a shortened version of previously used and validated 28-item Hospice Quality of Life Index (HQLI). It has 14 items; each item is scored on a 0-10 scale; the total score is obtained by adding item scores which range from 0-140, while 0 reflects the worst QOL that could be measured and 140 is the
The factor analysis of the HQLI revealed three factors which included: psycho-physiological, functional and social/spiritual wellbeing. Concurrent validity was supported by correlation which was analyzed in a hospice sample prior to the beginning of the study. Construct validity was evaluated by correlation with the original HQLI (r= 0.94, p< 0.001) (Buck, Overcash, & McMillan, 2009). Reliability of the HQLI was provided by generation of coefficient alphas for both total scale scores and subscale scores, Subscale alphas were .84 and the total alpha when it used with cancer patients was (r=.88) (McMillan & Mahon, 1994).

**Palliative Performance Scale (PPS).** The PPS was used to measure the functional status for patients. The PPS was developed by the Victoria Hospice Society in 1999. The PPS assesses a patient’s level of ambulation, activity, evidence of disease, self-care, intake, and consciousness. Patients can score between 0-100%; while 0 means death and 100 reflects a person with normal activity level. The PPS scale was designed to assess a patient’s functional level and the needs of palliative care patients. Construct validity was supported by the strong positive correlation between PPS and Karnofsky Functional Status (r= 0.93) (McMillan et al., 2010). Strong correlations were found between the scores rated by an oncologist, radiation therapist, and a research assistant (r=0.69-0.86). In addition, good reliability as measured by the alpha coefficient was reported (Campos et al., 2009).

**Short Portable Mental Status Questionnaire (SPMSQ).** Measures the presence of intellectual impairment and the degree of impairment in patients. Scores range from 0 to 10; a cutoff score of 8 was used in this study. This is a valid instrument to be used for detecting moderate to severe cognitive impairment in cancer patients (MacNeil &
Lichtenberg, 1999). Evidence was found for the reliability and reliability coefficients were greater than 0.80 (Pfeiffer, 1975).

**Demographic Data Form.** Included gender, age, race/culture, marital status, income, educational level, type of cancer, and physical/mental health status.

**Procedures**

For the parent study, the patients were identified by the research assistants, who were nurse data collectors who had been hired for the original study. These research assistants visited the homes of patients, consented the patients, and collected baseline data (McMillan, Small, & Haley, 2010).

For this secondary analysis, data was obtained from Dr. McMillan, who gave permission for its use. Data was cleaned by reviewing for missing data and by randomly selecting cases for double entry. Means of the cases that were double-entered compared with the sample means from patients already entered. If differences were found, the original data from the paper copies were reviewed to find the errors. These errors were corrected. Patients with missing data eliminated from the data set. The revised data set used for this proposed secondary analysis.

**Data Analysis**

This study was conducted through secondary analysis of data. First, data was analyzed using descriptive statistics, so the frequency, percentage, means and standard deviations for quality of life for the overall sample of hospice cancer patients were calculated along with all other variables. Correlation coefficients between quality of life
and patients' socio-demographic variables and between quality of life and clinical characteristics also were calculated.

Multivariate regression analysis was conducted using QOL as the dependent variable, and age, gender, education, functional and mental status, cancer diagnosis, and constipation severity as the predictor variables. An exploratory mediation analysis was used to assess the mediation effect of the constipation distress. A mediator can be explained as a transmitter of the effect of an independent variable (IV) on the dependent variable (DV). So the IV affects the DV because the IV affects the mediator, and the mediator in sequence affects the DV. (Preacher, Rucker, & Hayes, 2007). Statistical significance of the mediated effect can be calculated by dividing the estimate by its standard error and comparing the result with the standard normal distribution. For non-normality of data, both confidence limits for mediated effects and re-sampling methods could be used (MacKinnon & Fairchild, 2009). The bootstrapping method was used to measure the mediating variable effects because this method has high power and it does not make an assumption about normality compared to the Sobel test or Baron and Kenny test (Hayes, 2009).
Chapter Four: Results

The purpose of the proposed study was to determine, using an existing data set, predictors of QOL and to evaluate the mediating effect of constipation distress in patients who receive homecare from a large nonprofit hospice. This chapter includes three sections; the first section represents description for demographic variables and clinical characteristics regarding cancer diagnosis, constipation severity and intensity, and patient’s physical and mental health. In the second section, correlations between the predictors of QOL and the overall QOL; and the third section represent the mediation analysis.

Sample

The sample consisted of 310 patients; the majority of whom were white (96.9%) (Table 1). The sample had slightly more males (55.3%) than females. Patients in this sample tended to be married (63.6%), and the majority of patients in this sample were living with someone (93.4%). The patients’ ages ranged between 21 and 95 years old, with a mean age of 72.7 years (SD= 12.1). Only 4.1 % of the patients in the sample were under 50 years old, and more than half of this sample were 70 years and older. The level of education among these patients was assessed by asking about the number of years of education. The mean was 12.7 years of education (SD= 2.9) (Table 2). The most common site for primary cancer was the lung (34%) (Table 1).
Table 1. Frequency and Percent of Patients by Demographic Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>171</td>
<td>55.3</td>
</tr>
<tr>
<td>Female</td>
<td>138</td>
<td>44.7</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
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<td></td>
</tr>
<tr>
<td>Currently married</td>
<td>203</td>
<td>63.6</td>
</tr>
<tr>
<td>Not-married</td>
<td>107</td>
<td>18.5</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>299</td>
<td>96.9</td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
<td>0.4</td>
</tr>
<tr>
<td><strong>Cancer Diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>105</td>
<td>34.0</td>
</tr>
<tr>
<td>GI/Colorectal</td>
<td>79</td>
<td>25.6</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>33</td>
<td>10.9</td>
</tr>
<tr>
<td>Breast</td>
<td>16</td>
<td>5.6</td>
</tr>
<tr>
<td>Gynecological</td>
<td>15</td>
<td>5.2</td>
</tr>
<tr>
<td>Other</td>
<td>62</td>
<td>18.6</td>
</tr>
<tr>
<td><strong>Reported Constipation</strong></td>
<td>310</td>
<td>44.5</td>
</tr>
</tbody>
</table>
Table 2. Means and Standard Deviations of Patients’ Age, Education, PPS Scores, Constipation Severity Scores and Constipation Distress Scores

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>72.7</td>
<td>12.1</td>
</tr>
<tr>
<td>Years of Education</td>
<td>12.7</td>
<td>2.9</td>
</tr>
<tr>
<td>Physical Function (PPS)</td>
<td>57.1</td>
<td>10.9</td>
</tr>
<tr>
<td>Mental Status (SPMSQ)</td>
<td>9.23</td>
<td>0.9</td>
</tr>
<tr>
<td>Constipation Severity</td>
<td>2.44</td>
<td>1.1</td>
</tr>
<tr>
<td>Constipation Distress</td>
<td>2.47</td>
<td>1.3</td>
</tr>
<tr>
<td>QOL Scores</td>
<td>102.2</td>
<td>17.4</td>
</tr>
</tbody>
</table>

Descriptive Statistics

Constipation was present among 44.5% of the patients in the sample (Table 1). According to the sample, the mean for constipation severity was 2.44 (SD= 1.1), and the mean for constipation distress was 2.47 (SD= 1.3). PPS was used to evaluate patients’ physical health. The mean score was 57.1 (SD= 10.9), while the SPMSQ was used for patients’ mental health evaluation, and yielded a mean score of 9.23 (SD= 0.9). Mean quality of life was 102.7 (SD=17.4) (Table 2).

Correlations

Bivariate correlations were calculated between QOL total scores and the target variables. Weak significant correlations were found between QOL and patients’ age and education. Weak but significant correlations were found between PPS and SPMSQ, and between years of education and SPMSQ. There was also a significant negative correlation between constipation severity and QOL total (p=0.01), and another significant
correlation of 0.25 between constipation distress and QOL total (p=0.01). Finally, there was a significant strong correlation of 0.69 between constipation severity and constipation distress (p=0.01).

**Predictors**

A regression analysis using bootstrapping method was done to answer question number one: Do socio-demographic variables age, gender, marital status, race/culture, education, and socioeconomic status), clinical characteristics (type of cancer, physical and mental status) and constipation intensity predict quality of life in hospice patients with cancer? The results showed that age, ethnicity, constipation severity and functional status were significant predictors for QOL (P<0.05) (Table 4).

**Mediation**

The bootstrapping method was used to measure the mediating variable effects and significance. The bootstrapping analysis revealed direct, partial and total effects with standard errors and significance. This analysis was done to answer question number two: To what extent does constipation distress serve as a mediator in the relationship between constipation intensity and overall quality of life in hospice patients with cancer? Results are presented in Table 4.
Table 3: Pearson Correlation Coefficients between the Predictors and the QOL.

<table>
<thead>
<tr>
<th></th>
<th>PSMSQ Patients Age</th>
<th>PPS Total</th>
<th>Years of education</th>
<th>Constip. Severity</th>
<th>Constip. Distress</th>
<th>QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSMSQ</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td>-0.11&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.24&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.19&lt;sup&gt;c&lt;/sup&gt;</td>
<td>-0.10</td>
<td>-0.03</td>
<td>-0.02&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>n</td>
<td>(307)</td>
<td>(309)</td>
<td>(308)</td>
<td>(310)</td>
<td>(310)</td>
<td>(302)</td>
</tr>
<tr>
<td>Patients Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td>-0.09&lt;sup&gt;b&lt;/sup&gt;</td>
<td>-0.06</td>
<td>-0.08</td>
<td>-0.07</td>
<td>0.18&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>(306)</td>
<td>(305)</td>
<td>(308)</td>
<td>(308)</td>
<td>(299)</td>
<td></td>
</tr>
<tr>
<td>PPS Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td>-0.04</td>
<td>-0.11</td>
<td>-0.02</td>
<td>0.18&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>(704)</td>
<td>(310)</td>
<td>(310)</td>
<td>(301)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years of education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td>0.03</td>
<td>0.06</td>
<td>-0.12&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td></td>
<td>(309)</td>
<td>(309)</td>
<td>(300)</td>
<td></td>
<td></td>
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<tr>
<td>Constipation Severity</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>0.69&lt;sup&gt;c&lt;/sup&gt;</td>
<td>-0.24&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td></td>
<td></td>
<td>(311)</td>
<td>(302)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation Distress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.25&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>n</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(302)</td>
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</tr>
<tr>
<td>QOL</td>
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<tr>
<td>r</td>
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<tr>
<td>n</td>
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</table>

<sup>a</sup> P<0.05  
<sup>b</sup> P<0.01

A significant relationship between the dependent variable, QOL, and the independent variable, constipation severity, was found (p<0.05). Both, the direct effect of the independent variable on the mediator, constipation distress, as well as the direct effect...
of the mediator on the dependent variable, were significant (p<0.05). However, the direct path between the independent variable and dependent variable with the mediator was not significant (p=0.24), which, according to Baron and Kenny, indicates that constipation distress mediates the effect of constipation severity on the QOL (Baron & Kenny, 1986) (Table 3).

Table 4: Direct, Partial, and Total Effects of Bootstrapping Mediation Analysis.

<table>
<thead>
<tr>
<th>Effect</th>
<th>Unstandardized Coefficient</th>
<th>Standard error</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>N= 296</td>
<td>Standard error</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Effect**
  - Effect of IV on mediators: 0.79, 0.05, 0.00
  - Direct effect of mediator on DV: -1.98, 0.99, 0.04
  - Total effect of IV on DV: -2.91, 0.85, 0.00
  - Direct effect of IV on DV: -1.35, 1.15, 0.24

- **QOL Predictors**
  - Age: 0.23, 0.08, 0.00
  - Gender: -0.14, 1.90, 0.94
  - Education: -0.52, 0.31, 0.09
  - PPS total: 0.19, 0.09, 0.04
  - SPMSQ: 0.99, 1.06, 0.36
  - Ethnicity: -11.44, 5.34, 0.03
  - Cancer Diagnosis: -0.71, 1.99, 0.72
Bootstrapping analysis revealed a significant effect of the following control variables (covariates) on the QOL: age, PPS score, and ethnicity; all of these variables were significant at less than 0.05 levels. On the other hand, gender, education, SPMSQ, living arrangement, and type of cancer were not significant.

In this analysis, constipation distress was proposed as a mediator between constipation severity and QOL. The number of bootstrap resamples was 5000. The bias-corrected confidence interval on the 95% level of confidence showed that constipation distress had a mediation effect on the relationship between constipation severity and QOL. (Table 3)
Chapter Five: Discussion, Conclusions, and Recommendations

Discussion

The purpose of this study was to determine, using an existing data set, predictors of QOL and to evaluate the mediating effect of constipation distress in patients who receive homecare from a large non-profit hospice. This study was designed to address the following questions: To what extent does constipation distress serve as a mediator in the relationship between constipation intensity and overall quality of life in hospice patients with cancer?

Patients with cancer often experience constipation which may be a result of the cancer, low fiber diet, lack of activity or opioids (McMillan, 2004). In this study, both severity and distress from constipation were evaluated. The characteristic of symptom distress is known as the degree of discomfort associated with a symptom experienced by the patient (Sarna, Lindsey, Brecht, Dean, & McCorkle, 1994). Analyzing all symptom dimensions reflects the patient's interpretation of a symptom (Molassiotis, Wengstrom, & Kearney, 2010).

Constipation is common in patients with cancer because of their many risk factors, and in a cancer patient receiving opiates, constipation is inevitable. Unfortunately, this potentially serious problem is often overlooked and under-managed (McMillan, 2004). In this study 44.5% of the patients reported having constipation, and
more than 70% of patients with constipation described the severity as 2 or more on a scale from 0-4. This moderate to severe level of constipation was also dominant in a study conducted with a large hospice population of 50,641 patients (Strassels et al, 2010).

The literature supported that distress has an impact on the people with advanced cancer near the end of life QOL (McMillan & Small 2002). The patients on the study were asked about how much distress they had because of constipation; 92.6% had reported a level of distress that ranged from one to four with a 2.47 mean on a scale from 0-4. The level of distress in this study was congruent with the literature which showed a percentage of 50%-53% of patients experienced distress caused by their symptoms (Kirkova et al, 2007, Mehnert et al 2007). This means that both, the symptom intensity and distress as well as the relationship between constipation and quality of life need to be considered when nurses manage patients to achieve the best symptom management for cancer patients. A limitation for the study is that the constipation variables were asked and evaluated on a single scale from 0 to 4; this single item scale may not reflect all the clinically important signs and symptoms of constipation.

The study included 310 cancer patients near the end of life; however, less than half reported constipation on the MSAS leaving a sample of 310 for the mediation analysis. The sample had a wide range of different age groups, ranging between 21 and 95 years old, and the mean age was 72.7 years. Although there was a wide range of ages, only 4.1% of the patients in the sample were under 50 years old, and more than half of this sample were 70 years and older. The fact that the majority of patients in this study were over 70 years old may affect the generalizability of the study to all cancer patients.
Patients within this sample came from different ethnic backgrounds, including African-American, Hispanic, Asian-Pacific Islander, and white. However, the great majority of the patients (97%) were white. Thus, results are not generalizable to all cancer patients because cancer affects people of all races and ethnicities. This result probably occurred because relatively small numbers of minority cancer patients seek hospice services. Future studies should attempt to include larger numbers of minority patients. The majority of patients were living with someone and not alone. This finding was the result of the way in which patients were identified in the original study; all patients had to have a family caregiver. Thus, these results are not generalizable to patients who do not have family caregivers, who are receiving hospice care in nursing homes or assisted living facilities, or who are residing in a hospice house. The patients reported a fairly high level of quality of life (mean = 102.2; SD=17.4), which represents 73% of the highest score of 140. This score is similar to the mean of another group of 255 hospice patients with cancer studied earlier (McMillan & Weitzner, 1998).

The study yielded that age has a significant negative relationship with QOL (P<0.05) and this was supported by previous research (Hack et al., 2010). Age and ethnicity were significant predictors that correlated with the cancer patients’ QOL.

The SPMSQ was used as a screening instrument for cognitive impairment, and as a result the patients in the study had relatively high cognitive function; that is, patients with lower mental status were screened out of the study. This restricted range problem may explain why this relationship between mental health and QOL was not significant while the literature supported the influence of the patients’ mental health on their overall QOL (Kandasamy, 2011).
In this study the patients’ mean score for their physical status was 57.1 (SD=10.9), which means that they were fully conscious, but they needed occasional assistance with self-care, and their significant disease reduced their ambulation and activity level. Again, this variable had a restricted range because patients with scores below 40 were excluded from the study. Never-the-less, patients’ physical status correlated positively with their QOL (P<0.01) as might be expected.

The more severe constipation became the lower were the QOL scores reported; this seems like a reasonable finding; that is, it should be expected that as a symptom increases in intensity, the distress also would increase and would have a negative effect on the QOL. The strongest correlation in this study was found between constipation severity and constipation distress 0.69 (P<0.01), in an earlier study the researcher concluded that constipation distress increased with increasing its severity, and 69% of patients with constipation complained from high level of constipation distress (Kirkova et al, 2006).

In order to evaluate the mediation effect of constipation distress between the predictor variables and QOL, a bootstrapping mediation analysis was used rather than both Baron and Kenny’s or Sobel’s approach. An extra analysis done based on Baron and Kenny reflected a significant direct path between the constipation severity and QOL (P=0.00) and a trend of mediation effect on the direct path with the constipation distress as a mediator. The benefits of bootstrapping methods are the higher power and that bootstrapping does not make an assumption about normality. The patients’ age, gender, education, physical and mental health, ethnicity and type of cancer were covariates controlled for in the regression analysis.
The mediation effect was significant when the level of confidence for confidence intervals was 95% and number of bootstrap resamples was 5000. With this new information that constipation distress mediates the relationship between constipation intensity and QOL, nursing has additional evidence of the importance of symptom distress. Thus, nurses should assess constipation intensity but also should determine the extent to which it is distressing to the patient. If this is the case for constipation, it may also be true for other symptoms.

**Conclusions and Recommendations**

Cancer patients suffer from many symptoms that could be related to the cancer itself or the cancer treatments. The symptom intensity and distress as well as the relationship between constipation and quality of life need to be seen in a holistic approach to achieve the best symptom management for cancer patients. Oncology nurses should consider the predictors of the patients’ QOL in order to identify patients who may be at risk for poor future QOL.

Committed individuals have already conducted some important research in symptom management and end of life care for cancer patients (McMillan et al, 2010), but the relationships between the symptom and their effect on patients and also between all symptoms need to be addressed more in the literature. The sample as mentioned before was mostly white, alert and functioning, and further biased by having family around them. Further studies should be conducted to learn about patients who are from minority groups, are not mentally or functionally capable and who have less available support.
systems. In addition, developing better tools for assessing the symptom experience may help in improving symptom distress management and alleviating patients suffering.
References


